

AMENDED IN ASSEMBLY MARCH 13, 1997

CALIFORNIA LEGISLATURE—1997–98 REGULAR SESSION

**ASSEMBLY BILL**

**No. 221**

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**Introduced by Assembly Member Goldsmith**  
**(Coauthors: Assembly Members Aroner, Ashburn, Figueroa,**  
**Floyd, House, Leach, Margett, Oller, Richter, and Wayne)**  
**(Coauthors: Senators Leslie, Peace, and Solis)**

February 5, 1997

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An act to amend Sections 1206.5, 1241, and 2058 of the Business and Professions Code, and to add Section 1596.797 to the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

AB 221, as amended, Goldsmith. Health: blood glucose monitoring.

Existing law governs the practice of clinical laboratory technology and prohibits the performance of certain clinical laboratory tests unless specified conditions are met, including that the tests are performed by certain authorized health care personnel.

This bill would authorize a person to administer a blood glucose monitoring test to a minor child in his or her care and control, who has been diagnosed with diabetes, without meeting the requirements of the laws governing clinical laboratory technology if certain requirements are satisfied.

Existing law, the Medical Practice Act, prohibits the unauthorized practice of medicine, but also provides that it

does not prohibit service in the case of emergency, or the domestic administration of family remedies.

This bill would provide that the act shall not be construed to prohibit the ~~pricking of a finger for the administration of performance of a finger stick in performing~~ blood glucose testing for the purposes of monitoring ~~of~~ a minor child with diabetes in accordance with specified requirements.

Existing law provides for the licensure and regulation of child day care facilities by the State Department of Social Services.

This bill would authorize a child day care facility to perform blood glucose testing for the purposes of monitoring ~~of~~ a minor child with diabetes in accordance with specified requirements.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 1206.5 of the Business and  
2 Professions Code is amended to read:  
3 1206.5. (a) Notwithstanding subdivision (b) of  
4 Section 1206, no person shall perform a clinical laboratory  
5 test or examination classified as waived under CLIA  
6 unless the clinical laboratory test or examination is  
7 performed under the overall operation and  
8 administration of the laboratory director, as described in  
9 Section 1209, including, but not limited to,  
10 documentation by the laboratory director of the  
11 adequacy of the qualifications and competency of the  
12 personnel, and the test is performed by any of the  
13 following persons:  
14 (1) A licensed physician and surgeon holding a M.D. or  
15 D.O. degree.  
16 (2) A licensed podiatrist or a licensed dentist when the  
17 results of the tests can be lawfully utilized within his or  
18 her practice.  
19 (3) A person licensed under this chapter to engage in  
20 clinical laboratory practice or to direct a clinical  
21 laboratory.



1 (4) A person authorized to perform tests pursuant to  
2 a certificate issued under Chapter 7 (commencing with  
3 Section 1000) of Part 2 of Division 1 of the Health and  
4 Safety Code.

5 (5) A licensed physician assistant when authorized by  
6 a supervising physician and surgeon in accordance with  
7 Section 3502 or Section 3535.

8 (6) A person licensed under Chapter 6 (commencing  
9 with Section 2700).

10 (7) A person licensed under Chapter 6.5  
11 (commencing with Section 2840).

12 (8) A perfusionist when authorized by and performed  
13 in compliance with Section 2590.

14 (9) A respiratory care practitioner when authorized  
15 by and performed in compliance with Chapter 8.3  
16 (commencing with Section 3700).

17 (10) A medical assistant, as defined in Section 2069,  
18 when the waived test is performed pursuant to a specific  
19 authorization meeting the requirements of Section 2069.

20 (11) A pharmacist, when ordering drug  
21 therapy-related laboratory tests in compliance with  
22 subparagraph (B) of paragraph (4) of, or clause (ii) of  
23 subparagraph (A) of paragraph (5) of, subdivision (c) of  
24 Section 4046.

25 (12) Other health care personnel providing direct  
26 patient care.

27 (b) Notwithstanding subdivision (b) of Section 1206,  
28 no person shall perform clinical laboratory tests or  
29 examinations classified as of moderate complexity under  
30 CLIA unless the clinical laboratory test or examination is  
31 performed under the overall operation and  
32 administration of the laboratory director, as described in  
33 Section 1209, including, but not limited to,  
34 documentation by the laboratory director of the  
35 adequacy of the qualifications and competency of the  
36 personnel, and the test is performed by any of the  
37 following persons:

38 (1) A licensed physician and surgeon holding a M.D. or  
39 D.O degree.

1 (2) A licensed podiatrist or a licensed dentist when the  
2 results of the tests can be lawfully utilized within his or  
3 her practice.

4 (3) A person licensed under this chapter to engage in  
5 clinical laboratory practice or to direct a clinical  
6 laboratory.

7 (4) A person authorized to perform tests pursuant to  
8 a certificate issued under Chapter 7 (commencing with  
9 Section 1000) of Part 2 of Division 1 of the Health and  
10 Safety Code.

11 (5) A licensed physician assistant when authorized by  
12 a supervising physician and surgeon in accordance with  
13 Section 3502 or Section 3535.

14 (6) A person licensed under Chapter 6 (commencing  
15 with Section 2700).

16 (7) A perfusionist when authorized by and performed  
17 in compliance with Section 2590.

18 (8) A respiratory care practitioner when authorized  
19 by and performed in compliance with Chapter 8.3  
20 (commencing with Section 3700).

21 (9) A person performing nuclear medicine technology  
22 when authorized by and performed in compliance with  
23 Chapter 7.2 (commencing with Section 25625) of  
24 Division 20 of the Health and Safety Code.

25 (10) Any person when performing blood gas analysis  
26 in compliance with Section 1245.

27 (11) (A) A person certified as an “Emergency  
28 Medical Technician II” or paramedic pursuant to  
29 Division 2.5 (commencing with Section 1797) of the  
30 Health and Safety Code while providing prehospital  
31 medical care, a person licensed as a psychiatric technician  
32 under Chapter 10 (commencing with Section 4500) of  
33 Division 2, as a vocational nurse pursuant to Chapter 6.5  
34 (commencing with Section 2840) of Division 2, or as a  
35 midwife licensed pursuant to Article 24 (commencing  
36 with Section 2505) of Chapter 5 of Division 2, or certified  
37 by the department pursuant to Division 5 (commencing  
38 with Section 70001) of Title 22 of the California Code of  
39 Regulations as a nurse assistant or a home health aide,  
40 who provides direct patient care, so long as the person is

1 performing the test as an adjunct to the provision of  
2 direct patient care by the person, is utilizing a  
3 point-of-care laboratory testing device at a site for which  
4 a laboratory license or registration has been issued, meets  
5 the minimum clinical laboratory education, training, and  
6 experience requirements set forth in regulations adopted  
7 by the department, and has demonstrated to the  
8 satisfaction of the laboratory director that he or she is  
9 competent in the operation of the point-of-care  
10 laboratory testing device for each analyte to be reported.

11 (B) Prior to being authorized by the laboratory  
12 director to perform laboratory tests or examinations,  
13 testing personnel identified in subparagraph (A) shall  
14 participate in a preceptor program until they are able to  
15 perform the clinical laboratory tests or examinations  
16 authorized in this section with results that are deemed  
17 accurate and skills that are deemed competent by the  
18 preceptor. For the purposes of this section, a “preceptor  
19 program” means an organized system that meets  
20 regulatory requirements in which a preceptor provides  
21 and documents personal observation and critical  
22 evaluation, including review of accuracy, reliability, and  
23 validity, of laboratory testing performed.

24 (12) Any other person within a physician office  
25 laboratory when the test is performed under the  
26 supervision of the patient’s physician and surgeon or  
27 podiatrist who shall be accessible to the laboratory to  
28 provide onsite, telephone, or electronic consultation as  
29 needed, and shall: (A) ensure that the person is  
30 performing test methods as required for accurate and  
31 reliable tests; and (B) have personal knowledge of the  
32 results of the clinical laboratory testing or examination  
33 performed by that person before the test results are  
34 reported from the laboratory.

35 (13) A pharmacist, when ordering drug  
36 therapy-related laboratory tests in compliance with  
37 subparagraph (B) of paragraph (4) of, or clause (ii) of  
38 subparagraph (A) of paragraph (5) of, subdivision (c) of  
39 Section 4046.

1 (c) Notwithstanding subdivision (b) of Section 1206,  
2 no person shall perform clinical laboratory tests or  
3 examinations classified as of high complexity under CLIA  
4 unless the clinical laboratory test or examination is  
5 performed under the overall operation and  
6 administration of the laboratory director, as described in  
7 Section 1209, including, but not limited to,  
8 documentation by the laboratory director of the  
9 adequacy of the qualifications and competency of the  
10 personnel, and the test is performed by any of the  
11 following persons:

12 (1) A licensed physician and surgeon holding a M.D. or  
13 D.O. degree.

14 (2) A licensed podiatrist or a licensed dentist when the  
15 results of the tests can be lawfully utilized within his or  
16 her practice.

17 (3) A person licensed under this chapter to engage in  
18 clinical laboratory practice or to direct a clinical  
19 laboratory when the test or examination is within a  
20 specialty or subspecialty authorized by the person's  
21 licensure.

22 (4) A person authorized to perform tests pursuant to  
23 a certificate issued under Chapter 7 (commencing with  
24 Section 1000) of Part 2 of Division 1 of the Health and  
25 Safety Code when the test or examination is within a  
26 specialty or subspecialty authorized by the person's  
27 certification.

28 (5) A licensed physician assistant when authorized by  
29 a supervising physician and surgeon in accordance with  
30 Section 3502 or Section 3535.

31 (6) A perfusionist when authorized by and performed  
32 in compliance with Section 2590.

33 (7) A respiratory care practitioner when authorized  
34 by and performed in compliance with Chapter 8.3  
35 (commencing with Section 3700).

36 (8) A person performing nuclear medicine technology  
37 when authorized by and performed in compliance with  
38 Chapter 7.2 (commencing with Section 25625) of  
39 Division 20 of the Health and Safety Code.



(9) Any person when performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory when the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as physician-performed microscopy under CLIA may be performed by a licensed physician and surgeon holding a M.D. or D.O. degree.

(e) Notwithstanding any other provision of law, a person who performs blood glucose ~~monitoring upon~~ *testing for the purposes of monitoring* a minor child diagnosed with diabetes pursuant to subdivision (c) of Section 1241 may do so without satisfying the requirements of this chapter, unless prohibited by federal law.

SEC. 2. Section 1241 of the Business and Professions Code is amended to read:

1241. (a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and

1 Human Services has modified the application of CLIA  
2 requirements to those laboratories.

3 (2) Public health laboratories, as defined in Section  
4 1206.

5 (3) Those that perform clinical laboratory tests or  
6 examinations for forensic purposes only.

7 (4) Those that perform clinical laboratory tests or  
8 examinations for research and teaching purposes only  
9 and do not report or use patient-specific results for the  
10 diagnosis, prevention, or treatment of any disease or  
11 impairment of, or for the assessment of the health of, an  
12 individual.

13 (5) Those that perform clinical laboratory tests or  
14 examinations certified by the National Institutes on Drug  
15 Abuse only for those certified tests or examinations.  
16 However, all other clinical laboratory tests or  
17 examinations conducted by the laboratory are subject to  
18 this chapter.

19 (c) This chapter shall not apply to persons who  
20 perform blood glucose—~~monitoring upon testing for the~~  
21 *purposes of monitoring* a minor child diagnosed with  
22 diabetes when the person performing the test has been  
23 entrusted with the care and control of the child by the  
24 child's parent or legal guardian and provided that all of  
25 the following occur:

26 (1) The ~~clinical-laboratory~~ *blood glucose monitoring*  
27 test is performed with a ~~kit~~ *blood glucose monitoring*  
28 *instrument* that has been approved by the federal Food  
29 and Drug Administration for sale ~~over the counter~~ to the  
30 public without a ~~prescription in the form of an~~  
31 ~~over-the-counter test kit.~~ *prescription.*

32 (2) The person has been ~~instructed in the proper use~~  
33 ~~of the kit, including the appropriate procedure for~~  
34 ~~obtaining a blood specimen with the use of the kit and the~~  
35 ~~proper method for handling and disposing of any~~  
36 ~~blood-borne pathogens or sharps from use of the kit.~~  
37 *provided written instructions by the child's health care*  
38 *provider or an agent of the child's health care provider in*  
39 *accordance with the manufacturer's instructions on the*



1 *proper use of the monitoring instrument and the*  
2 *handling of associated medical waste.*

3 (3) The person, receiving authorization from the  
4 minor's guardian, complies with written instructions  
5 from the child's health care provider, ~~parent, or guardian~~  
6 ~~regarding~~ *or an agent of the child's health care provider,*  
7 *regarding the performance of the test and the operation*  
8 *of the blood glucose monitoring instrument, including*  
9 *how to determine if the test results are within the normal*  
10 *or therapeutic range for the child.*

11 (4) The person complies with *specific written*  
12 *instructions from the child's health care provider,* ~~parent,~~  
13 ~~or guardian regarding action~~ *or an agent of the child's*  
14 *health care provider regarding actions to be taken when*  
15 ~~test~~ *results are not within the normal or therapeutic*  
16 *range for the child.*

17 SEC. 3. Section 2058 of the Business and Professions  
18 Code is amended to read:

19 2058. (a) Nothing in this chapter prohibits service in  
20 the case of emergency, or the domestic administration of  
21 family remedies.

22 (b) Nothing in this chapter shall be construed to  
23 prohibit the ~~pricking of a finger~~ *performance of a finger*  
24 *stick* in performing blood glucose ~~monitoring upon~~  
25 *testing for the purposes of monitoring* a minor child in  
26 accordance with subdivision (c) of Section 1241.

27 SEC. 4. Section 1596.797 is added to the Health and  
28 Safety Code, to read:

29 1596.797. A child day care facility may perform blood  
30 glucose ~~monitoring upon~~ *testing for the purposes of*  
31 *monitoring* a minor child diagnosed with diabetes in  
32 accordance with subdivision (c) of Section 1241 of the  
33 Business and Professions Code.